Supreme Court, U.S.
FILED

No. _____ 10-247

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In The

Supreme Court of the United States

CATHIE WELLER, Individually
and as the personal representative of
the Estate of James Hetherington,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Eleventh Circuit

PETITION FOR WRIT OF CERTIORARI

CATHIE WELLER
Pro Se
28246 Nuke Whitt Lane
Ardmore, Al 35739
256-423-7469
cwx2@ardmore.net

QUESTION PRESENTED FOR REVIEW

The Supreme Court of the United States may grant a petition for writ of certiorari when there is a "Circuit Split", if at least two Appeals Courts rule differently in a similar situation. The petition may also be granted to clear up any confusion on legal issues of national importance by establishing a nationally uniform understanding in Federal Rules of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc. on what the rule actually instructs and empowers a trial judge to do.

Did the United States Court of Appeals for the Eleventh Circuit err in ruling against the Plaintiff-Appellant in the case of Petitioner Cathie Weller v. United States of America?

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The opinion of the United States Court of Appeals for the 11th Circuit appears at APPENDIX PAGE 1 to the petition and is unpublished.

The opinion of the United States District Court for the Northern District of Alabama appears at APPENDIX PAGE 7 to the petition and is unpublished.

BASIS FOR JURISDICTION IN THIS COURT

This action was filed in the United States District Court for the Northern District of Alabama. The court entered judgment in favor of Defendants on November 18, 2009. Petitioner timely appealed to the United States Courts of Appeals for the 11th Circuit. The United States Court of Appeals for the 11th Circuit entered judgment in favor of Defendant-Appellee on May 20, 2010. No petition for rehearing was filed. This petition is timely filed under Supreme Court Rule 13(1), and this court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

Pursuant to Supreme Court Rule 14(e), Petitioner provides the following specific information:

Date the judgment or order sought to be reviewed was entered:

May 20, 2010 by the United States Court of Appeals for the 11th Circuit

Date of any order respecting rehearing/extension of time:

Not applicable to this Petition

Rule 12.5 considerations:

Not applicable to this Petition

Statutory provision conferring jurisdiction:

28 U.S.C. § 1254(1)

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Not applicable to this Petition

STATUTES INVOLVED

28 U.S.C. § 1346.

(b)

(1) Subject to the provisions of chapter 171 of this title, the district courts, together with the United States District Court for the District of the Canal Zone and the District Court of the Virgin Islands, shall have exclusive jurisdiction of civil actions on claims against the United States, for money damages, accruing on and after January 1, 1945, for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment, under circumstances where the United States, if a private person, would

be liable to the claimant in accordance with the law of the place where the act or omission occurred.

(2) No person convicted of a felony who is incarcerated while awaiting sentencing or while serving a sentence may bring a civil action against the United States or an agency, officer, or employee of the Government, for mental or emotional injury suffered while in custody without a prior showing of physical injury.

(c) The jurisdiction conferred by this section includes jurisdiction of any set-off, counterclaim, or other claim or demand whatever on the part of the United States against any plaintiff commencing an action under this section.

(d) The district courts shall not have jurisdiction under this section of any civil action or claim for a pension.

(e) The district courts shall have original jurisdiction of any civil action against the United States provided in section 6226, 6228(a), 7426, or 7428 (in the case of the United States district court for the District of Columbia) or section 7429 of the Internal Revenue Code of 1986.

(f) The district courts shall have exclusive original jurisdiction of civil actions under section 2409a to quiet title to an estate or interest in real property in which an interest is claimed by the United States.

(g) Subject to the provisions of chapter 179, the district courts of the United States shall have

exclusive jurisdiction over any civil action commenced under section 453(2) of title 3, by a covered employee under chapter 5 of such title.

STATEMENT OF THE CASE

Petitioner's father, James Hetherington, began healthcare treatment at the Louis Stokes Veterans Administration Medical Center (Cleveland VAMC), in Cleveland, Ohio in February 2003. What began as a persistent "flu-like" illness ended with Toxic Epidermal Necrolysis (TENS) and death on September 16, 2003.

The concise version of what happened on September 16th is as follows: The patient was intubated in the morning with wife present. Petitioner and brother arrived around 12:30 p.m. The patient, minutes later, was prepped for transfer to the Cleveland Metro Burn Unit Hospital (CMBU). We were told by the Cleveland VAMC to head to CMBU. Upon arrival, the greeting nurse told us to go have lunch for the next hour. During that hour, we were summoned to a private room to wait on a Doctor. Dr. Yowler informed us that the patient had passed away approximately ½ hour ago from TENS, florid septic shock and consequently, heart failure. This was the first time we had ever, under any set of circumstances, heard the words "TOXIC EPIDERMAL NECROLYSIS."

The petitioner's "grounds" to investigate the possibility of medical malpractice and wrongful death lawsuit claims against the Cleveland VAMC began with research on line and later with the retrieval and reading of over 2,000 pages of Cleveland VAMC medical records.

It all had to begin with research on what TENS was by definition:

(1) Stevens Johnsons Syndrome "skin loss"= less than 10% total body skin;

(2) Transitional SJS/Toxic Epidermal Necrolysis "skin loss"=10%-30%; and

(3) "Full blown" TENS=greater than 30% skin loss

According to the CMBU records, patient had 100% rash with 58% skin loss.

Next was research on "the standard of care" with regard to following proper protocol:

(1) Early diagnosis and recognition; (2) Withdrawal of all potential causative drugs; (3) Sterile ICU environment; and (4) prompt transfer to a burn unit.

Next was the step to find legal representation for alleged medical malpractice and wrongful death. Petitioner was unsuccessful in obtaining counsel for contractual representation. Therefore, a Standard Form 95(SF95) was completed and mailed by Petitioner, Pro Se, on September 9, 2005 by certified/

priority mail through the U.S. Postal Service with expected delivery on September 12th or 13th, well within the 2 year statute of limitations.

Delivery of the SF95 was made on September 20, 2003 by the United States Postal Service. The final denial letter was dated March 29, 2007 from The Department of Veterans Affairs Office of the General Counsel in Washington, D.C.

Petitioner was instructed that if dissatisfied with the decision for denial on 2 grounds: (1) no evidence of James Hetherington suffering injury or death from a negligent or wrongful act on the part of a VA employee; and (2) petitioner was untimely with the SF95 filing, thus barred by the 2 year statute of limitations contained in 28 U.S.C. § 2401(b), the Federal Tort Claims Act (28 U.S.C. §§ 1346(b), 2671-2680) permitted the filing of a lawsuit within 6 months from the above dated letter of March 29, 2007.

On September 19, 2007, Petitioner filed her case, Pro Se, as: Cathie Weller, individually and as the personal representative of the Estate of James Hetherington v. The United States of America in the United States District Court for the Northern District of Alabama. CASE No. CV-07-C-1706-NE.

Jurisdiction 28 U.S.C. § 1331; Federal Tort Claims Act (28 U.S.C. §§ 1346(b), 2671-2680) alleged medical malpractice and wrongful death by the Veterans Administration (VA Hospital), per the instructions from the March 29, 2007 denial letter by the Assistant General Counsel from the Department

of Veterans Affairs, "If you decide to initiate such a suit, you are further advised that the proper party defendant would be the United States, not V.A."

Petitioner argued in her statement of claim that the 2 year statute of limitations issue should accrue from the time the plaintiff knows of both the existence AND cause of injury or at a later time when known that the acts inflicting the injury have constituted medical malpractice. In this situation, the official Ohio Certificate of Death was filed by the Coroner on October 1, 2003. When this document was received by Petitioner, it was then revealed what caused the decedent's TENS disease, not before. "Toxic Epidermal Necrolysis due to multiple prescribed medications – Plavix, Ticlid and/or Metoprolol."

On January 8, 2008, U.S. District Judge U.W. Clemon found that a genuine issue of material fact existed with respect to when the claim accrued resulting in denial of defendant's motion for summary judgment. Civil Action No. 5:07-CV-01706-UWC

On February 1, 2008, an amended complaint, Case 5:07-CV-01706-UWC was filed by the law firm of record, Rawls & McNelis, P.C., Richmond, Va., on behalf of the Plaintiff-Petitioner.

Decided on November 18, 2009, Civil Action No. CV-07-S-01706-NE by U.S. District Judge C. Lynwood Smith, (1) The District Court denied summary judgment in favor of the Plaintiff on the first ground, finding that "a genuine issue of material fact remains

as to the precise date upon which plaintiff discovered or, in the exercise of reasonable diligence, should have discovered the acts constituting the alleged malpractice." (2) Government's (defendant) motion to exclude the testimony and opinions of plaintiff's expert's and for summary judgment was granted and all of plaintiff's claims are dismissed with prejudice. APPENDIX PAGE 7

An appeal was filed on February 8, 2010 in the United States Court of Appeals for the 11th Circuit by the same firm, Rawls & McNelis Case No. 09-16378cc. APPENDIX PAGE 1 The reason for the appeal was that the district court abused its discretion in granting summary judgment in favor of the defendants (Government): (1) that the expert designations of Dr. Edward Taylor and Dr. Alan Moshell were insufficient under Daubert and Merrell Dow; (2) that their theories of causation are unreliable as required by Federal Rules of Evidence 702.

Decision Filed May 20, 2010 from the U.S. Court of Appeals for the 11th Circuit, D.C. No. 07-01706-CV-CLS [Do not Publish]. APPENDIX PAGE 1

Summary judgment in favor of the government (Appellee) was given because the court gives "considerable leeway" to the lower court in the execution of its duty and concluded that the district court did not abuse its discretion in excluding plaintiff's pro offered expert testimony. The doctors used a "differential diagnosis" methodology in reaching their opinions as to causation.

According to Judge Lynwood Smith in Petitioner's CIVIL ACTION No.CV-07-S-01706-NE, decided November 18, 2009, "Both experts' reports simply review notations made by the treating physicians at the Cleveland VAMC and make speculative opinions as to causation without disclosing any reasoning. The opinions of Dr. Taylor and Dr. Moshell, therefore, add nothing to plaintiff's case apart from what plaintiff's lawyers could argue to the jury." APPENDIX PAGE 59

(Federal Tort Claims Act civil proceedings (lawsuit) do not permit a jury. Bench trial only.)

Petitioner's expert Dr. Edward Taylor, Board Certified in Internal Medicine, stated in his report filed April 15, 2009 in the U.S. District Court of Northern District of Alabama, Case 5:07-CV-01706-CLS (Document 54-2)

> Stevens Johnson Syndrome or Toxic Epidermal Necrolysis are problems that are always in the forefront of any qualified clinicians mind when evaluating a patient with a severe or suspicious appearing rash. Since progression of the rash can be rapid and because the end result can be sepsis and death, it is paramount that measures be taken early on to avoid catastrophe. There is no question that Reverend Hetherington had a rash and other systemic symptoms that should have (and in fact did) trigger a search for an inciting agent. Medications are the most common cause of Stevens Johnson Syndrome or Toxic Epidermal Necrolysis. The standard of care

> at any treatment center adhering to reasonable standards is to stop all medications possible and not restart them until an inciting agent is identified. This was not done in a timely manner and the failure to do so is a breach of the standard of care. Studies have shown that the earlier the causative drug is removed, the better the prognosis. A patient should then be considered "allergic" to the causative agent and it should never be administered again.

Petitioner's expert Dr. Alan Moshell stated in his report filed April 15, 2009 in the U.S. District Court in the Northern District of Alabama Case 5:07-CV-01706-CLS (Document 54-2)

> I am a Board Certified Dermatologist . . . as such my practice includes the evaluation and treatment of patients with Stevens Johnson Syndrome and TEN (Toxic Epidermal Necrolysis) . . . The prudent course in such a situation is for medications to be withheld. If medication is absolutely required for a given condition, every effort should be made to switch the patient to a medication that is chemically dissimilar to the one he or she had been on previously.

ARGUMENT FOR GRANTING THE WRIT

I. The court should grant this petition for writ of certiorari to prevent further confusion in the lower courts on how to properly interpret the Federal Rule of Evidence 702 (Daubert) by all trial judges. The Petitioner will point out how the lower courts' erroneous decisions are an issue of national importance, not only with this case, but those who seek justice in similar situations and why Petitioner's case, Cathie Weller v. United States of America, should have had the same favorable decision as David L. Best v. Lowe's Home Centers Inc., 563 F.3d 171 (6th Cir. 2009) No. 08-5924 resulting in the opportunity for a trial to show alleged wrong doing on the part of the Defendant-Appellee, the United States of America

Rule 702 of Federal Rules of Evidence, provides that,

> if scientific, technical or other specialized knowledge will assist the Trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify there to in the form of an opinion or otherwise if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods and (3) the witness has applied

> the principles and methods reliably to the facts of the case.

The lower court in David L. Best v. Lowe's Home Centers, Inc., 563 F.3d 171 (6th Cir. 2009) concluded that Dr. Moreno's opinion was faulty for "failure to consider other possible causes." In light of Dr. Moreno's testimony that testing the effects of "hazardous chemicals" on humans was not appropriate, the district court decided not to hold the lack of such testimony against him.

Dr. Moreno used the "differential diagnosis" method in forming his opinion, which determines what disease process caused a patient's symptoms. A physician considers all relevant potential causes of the symptoms and then eliminates alternative causes based on a physical examination, clinical tests, and a thorough case history. Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255, 260 (6th Cir. 2001) (Quoting Federal Judicial Center reference manual on scientific evidence 214 (1994)), the 6th Circuit recognizes differential diagnosis as, "an appropriate method for making a determination of causation for an individual instance of disease." Hardyman, 243 F.3d at 260. An "Overwhelming majority of the courts of appeals agree, and have held 'that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid to satisfy the first prong [reliability] of the Rule 702 inquiry.'" Westberry v. Gislaved Gummi AB, 178 F.3d 257, 263 (4th Cir. 1999) (collecting cases from the First, Second, Third, Ninth and D.C. Circuits). The district court did not

cite Hardyman or any other cases that discuss the admissibility of causation opinions based on the method of differential diagnosis. The 6th Circuit goes on to say that they would use the Denovo method for an admissible opinion under Rule 702.

The 3rd Circuit noted that the "differential diagnosis generally is a technique that has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results." It also emphasized the individual nature of each differential diagnosis. "[The] steps a doctor has to take to make [a] (differential diagnosis reliable are likely to vary from case to case.")

"There is no requirement that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness." Kudabeck v. Kroger Co., 338 F.3d 856, 862 (8th Cir. 2003)

Another 2nd Circuit case, McCullock v. H.B. Fuller Co., 61 F.3d 1038 (2nd Cir. 1995), discusses how even when medical literature could not prove that throat polyps were the result of breathing hot glue fumes, the court admitted the doctor's testimony, comparing the situation with Dr. Moreno's testimony. The court said that, "Lowe's makes much of Dr. Moreno's failure to eliminate Lescol as a possible cause. But Doctor's need not rule out every conceivable cause in order for their differential diagnosis-based opinions to be admissible." E.g., Westberry v. Gislaved Gummi AB, 178 F.3d 257, 266 (4th Cir.

1999) (citing In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 764-65 (3d Cir. 1994)). "Lowe's presented no evidence that Lescol might cause anosmia. If such evidence exists, or if Dr. Moreno failed to consider some other likely cause, Lowe's is free to attack Dr. Moreno's opinion at trial." The court stated that Dr. Moreno's diagnosis might not stand up to exacting scrutiny if he were testifying as a research scientist or a chemist, but he is neither of those. He performed as a competent, intellectually rigorous treating physician in identifying the most likely cause of Best's injury. Any weaknesses in his methodology will affect the weight that his opinion is given at trial, but not its threshold admissibility. See, e.g., Kudabeck v. Kroger Co., 338 F.3d 856, 861-62 (8th Cir. 2003) ("[A]ttacks regarding the completeness of [A doctor's] methodology go to the weight and not the admissibility of his testimony."); Heller v. Shaw Indus., Inc., 167 F.3d 146, 157 (3d Cir. 1999) (describing a case in which the "district court erred in excluding expert medical testimony because a defendant's suggested alternative causes (once adequately addressed by plaintiff's expert) affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony").

Lowes pointed out several problems with Dr. Moreno's expert opinion. The court said, "But our function is not to determine whether the opinion is air tight and conclusively proves the cause of Best's anosmia. Rather, the court's role as gatekeeper is to decide whether Dr. Moreno performed his duties as a

diagnosing physician to the professional level expected in his field." See Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). "In light of this statement, we conclude that Dr. Moreno's differential diagnosis testimony meets the threshold level of admissibility under Daubert."

The court concludes by saying,

> We further note that, even without Dr. Moreno's expert testimony, summary judgment might be inappropriate in this case in light of this court's recent decision in Gass v. Marriott Hotel Services, 558 F.3d 419, 434 (6th Cir. 2009) (holding that expert testimony was not required to prove the causation element of a negligence case where the plaintiffs were allegedly exposed to pesticides and immediately developed respiratory injuries. Because we conclude that Dr. Moreno's opinion is admissible, however, we have no need to decide whether the holding in Gass is applicable to the present case.

The Sixth Circuit decided in favor of the plaintiff-appellant with a reverse of judgment from the lower court, U.S. District Court for the Eastern District of TN at Knoxville, and a remand for further proceedings.

II. The United States Court of Appeals for the Eleventh Circuit's decision in Cathie Weller, Individually and as the personal representative of the Estate of James Hetherington v. United States of America (D.C. Docket No. 07-01706-CV-CLS [UNPUBLISHED] in Appendix No. 1), conflicts with David L. Best v. Lowe's Home Centers, Inc. 563 F.3d 171 (6th Cir. 2009) (No. 08-5924)

The United States Court of Appeals for the Eleventh Circuit dismissed the petitioner's case May 20, 2010 on appeal from the United States District Court for the Northern District of Alabama. The court states that they review a district court's decision to exclude an expert's testimony under an "abuse of discretion standard." This standard of review requires that we defer to the district court's ruling unless it is "manifestly erroneous." Because the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under Daubert . . . we give the district court "considerable leeway" in the execution of its duty, concluding that the district court did not abuse its discretion in excluding the plaintiff's proffered expert testimony.

Dr. Edward Taylor and Dr. Alan Moshell claim to have used the "differential diagnosis" method in reaching their opinions as to causation. The court said that there was no indication that either expert compiled a "comprehensive list" of potential causes of the decedent's illness or explained why potential

alternative causes were ruled out. Both experts admit in their depositions that they failed to rule out the "potential" role of other drugs that the decedent was taking in causing his fatal illness. The district court found, based on these failures, the experts failed to apply differential diagnosis methodology reliability in their respective evaluations. The district court further found that, because of these failures, the experts' testimonies would not assist the trier of fact. For these reasons, the district court concluded that the testimony of both experts should be excluded under Rule 702 and Daubert, and it did not abuse its discretion in so concluding.

This court ends by stating, "Finally, the district court was correct that, without testimony of those two experts, the plaintiff had no evidence as to causation. Accordingly, summary judgment in favor of the government was proper." Affirmed. APPENDIX PAGE 1

Petitioner has pointed out thus far, "the circuit court split" example between Best v. Lowe's and Weller v. U.S.A. in the argument with the appellate court system.

This next example will be the lower court conflict between the petitioner's decision by Judge Smith and Globetti v. Sandoz Pharmaceuticals, Corporation, 111 F. Supp. 2d 1174 (2000). U.S. District Court for the Northern District of Alabama Southern Division.

The United States District Court for the Northern District of Alabama, Northeastern Division,

Judge Lynwood Smith, dismissed this petitioner's case on November 18, 2009 in favor of the Government, the defendant, on a motion for summary judgment to exclude the testimony of plaintiff's medical witnesses on the issue of causation and the applicable standard of care, arguing that their opinions are not reliable.

Judge Smith states, "In the absence of evidence to support plaintiff's theory of causation, the Government's motion for summary judgment also must be, and accordingly will be, granted." APPENDIX PAGE 7

In Globetti v. Sandoz Pharmaceuticals Corporation, 111 F. Supp. 2d 1174 (2000), much of the same legal application from Best v. Lowe's is evident here as well.

Chief United States Magistrate Judge Putnam states, "The gatekeeping role of the trial court requires flexibility and a practical recognition of what can be known and how it is known. If scientific methodologies can validate certain facts, scientifically reasonable inferences drawn from those facts are admissible. Daubert did not erect insurmountable obstacles to the admissibility of expert opinion evidence, rather, it simply holds that before expert-opinion evidence should be allowed, the opinion should be based on "good grounds", that is, "supported by appropriate validation – i.e., good grounds based on what is known." Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 590, 113 S. Ct. 2786

(1993). "The point of the gatekeeping role is to separate opinion evidence based on 'good grounds' from simple subjective speculation masquerading as scientific knowledge."

> The assessment process, that is, the process of examining whether "good grounds" exist, focuses on the methodologies the witness used to reach the opinion he or she will express, not the scientific correctness of the opinion. It is not part of the trial judge's gatekeeping role to determine whether the proffered opinion is scientifically correct or certain in the way one might think of the law of gravity. The gatekeeping role is addressed to mere evidentiary admissibility; it is the fact-finders role (usually a jury) to determine whether the opinion is correct or worthy of credence. For the trial court to overreach in the gatekeeping function and determine whether the opinion evidence is correct or worthy of credence is to usurp the jury's right to decide the facts of the case. All the trial judge is asked to decide is whether the proffered evidence is based on "good grounds" tied to the scientific method.

The court found that the expert testimony in this case on behalf of the plaintiff, Mrs. Globetti, was scientifically reliable under Daubert and Federal Rule 702. Consequently, plaintiffs showed there to be a triable issue of medical causation. The defendant's motion for summary judgment on medical causation was denied.

The climactic conclusion is to show this Honorable Court what this petitioner will produce as documented facts for "good grounds" evidence.

The medical records of the decedent written by the treating physicians at the Cleveland VAMC are a matter of record and are clear. Dr. Moshell and Dr. Taylor did not write them. As this case is an alleged medical malpractice and wrongful death F.T.C.A lawsuit, the medical records are the only source of "what really happened" from August 24 until September 16, 2003.

In closing, I the Petitioner, will help this Honorable Court to understand why my experts should have been allowed to testify at the trial my family and I never had.

1. August 24-September 16, 2003 (24 days)

(A) The decedent, James Hetherington, adamantly refused Metoprolol on two occasions, Sept 8th and 13th for fear it was causing his rash.

(B) There is no written documentation in the medical records where he gave his consent to resume Metoprolol. An "Apples to Apples" analogy here is, if a doctor documents the refusal, it should also be documented for permission to resume. Decedent was put back on Metoprolol Sept. 2nd, 5th, and the 14th. Also on the 14th, two days before his death, fourteen other medications were given to the decedent, in light of the fact the records

clearly state that the treating physicians knew of his SJS/TENS disease and should have known the proper protocols.

(C) August 24th – day of admission – rash

August 25th – Metoprolol suspected along with SJS with possibility of the progression to TENS.

August 27th – Concurred findings by an infectious disease doctor

August 29th – Skin biopsy positive for drug rash

2. The death certificate signed on Sept. 30, 2003, and issued Oct. 1, 2003 by the Cuyahoga County Ohio Medical Examiner stated as cause of death: "Toxic Epidermal Necrolysis due to multiple prescribed medications Plavix, Ticlid and/or Metoprolol."

(A) Plavix and Ticlid were discontinued shortly after the August 24th admission, metoprolol however, was restarted again on Sept. 2nd. How did the Medical Examiner know which "3" drugs to list on the death certificate since no autopsy was performed? As referenced earlier in Globetti v. Sandoz Pharmaceuticals Corporation, No. CV-98-TMP-2649-S; 111 F. Supp. 2d 1174 (2000) U.S. District Court Northern District of Alabama, Southern Division, Chief U.S. Magistrate Judge Putnam states, "What can

be known and how it is known . . . " applies here in this petitioner's case.

3. Finally, in General Electric Co. et al. v. Joiner et ux. Certiorari to the United States Court of Appeals for the 11th Circuit No. 96-188; Argued October 14, 1997 – Decided December 15, 1997 CITE AS: 522 U.S. 136 (1997) Opinion of Stevens, J. Pg 155 says "And nothing in either Daubert or the Federal Rules of Evidence requires a district judge to reject an experts conclusions and keep them from the jury when they fit the facts of the case and are based on reliable scientific methodology."

CONCLUSION

When I, the Petitioner, filed my Standard Form 95 Pro Se September 9, 2003, it was because I knew I had "good grounds," for the pursuit of justice.

When I, the Petitioner, filed my FTCA lawsuit Pro Se, September 17, 2007, it was because I STILL knew I had "good grounds," for the pursuit of justice.

When I, the Petitioner, filed my writ of certiorari Pro Se, August 18, 2010, it was because I knew I had "good grounds," – this time of National importance – not just for me, but for all those that

follow in their pursuit of justice and by having their day in court.

Respectfully submitted,

CATHIE A. WELLER
Pro Se Petitioner
Individually and as the
Personal Representative of the
Estate of James Hetherington
28246 Nuke Whitt Lane
Ardmore, Al 35739
256-423-7469

Dated: August 18, 2010

[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 09-16378
Non-Argument Calendar

D. C. Docket No. 07-01706-CV-CLS

CATHIE WELLER,
individually and as the personal
representative of the Estate of
James Hetherington,

Plaintiff-Appellant,

versus

UNITED STATES OF AMERICA,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Alabama

(May 20, 2010)

Before DUBINA, Chief Judge, CARNES and MARCUS, Circuit Judges.

PER CURIAM:

Appellant Cathie Weller filed this action in the district court, asserting claims under the Federal Tort Claims Act, 28 U.S.C. § 1346(b)(1) and §§ 2671-2680. Both parties moved for summary judgment. Appellee United States of America moved for summary judgment on two grounds. The first ground-that Appellant's claims were time-barred because she did not file a claim with the appropriate federal agency within two years of her decedent's death-was rejected by the district court. However, the district court granted summary judgment in favor of Appellee on its second asserted ground. Specifically, the district court found that the testimony of plaintiff's experts on the issue of causation was unreliable and, therefore, inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merell Dow Pharmaceuticals, Inc., 509* U.S. 579 (1993). Without the testimony of those witnesses, there was no evidence of causation and, accordingly, the district court concluded that summary judgment in favor of the government was appropriate.

"We review a district court's decision to exclude an expert's testimony under an abuse of discretion standard." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). "This standard of review requires that we defer to the district court's

ruling unless it is 'manifestly erroneous.'" *Id.* (quoting *Quiet Tech. DC-8, Inc. v. Hurd-Dubois UK Ltd.*, 326 F.3d 1333, 1340 (11th Cir. 2003)). "Because the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court under *Daubert* . . . we give the district court 'considerable leeway' in the execution of its duty." *Id.* (quoting *Kumho Tire*, 526 U.S. at 152) (internal citations omitted).

Applying this standard to the facts of this case, we conclude that the district court did not abuse its discretion in excluding the plaintiff's proffered expert testimony. As noted by the district court, both of the plaintiff's experts, Dr. Edward Taylor and Dr. Alan Moshell, claim to have utilized what is referred to as the "differential diagnosis" methodology in reaching their opinions as to causation. However, as is required in applying that methodology, there is no indication that either expert compiled a "comprehensive list" of potential causes of the decedent's illness or explained why potential alternative causes were ruled out. Both experts admit in their respective depositions that they failed to rule out the potential role of other drugs that the decedent was taking in causing his fatal illness.

The district court found that, based on these failures, the experts failed to apply the differential diagnosis methodology reliably in their respective evaluations. The district court further found that, because of these failures, the experts' testimonies would not assist the trier of fact. For these reasons,

the district court concluded that the testimony of both experts should be excluded under Rule 702 and *Daubert*. The district court did not abuse its discretion in so concluding.

Finally, the district court was correct that, without the testimony of these two experts, the plaintiff had no evidence as to causation. Accordingly, summary judgment in favor of the government was proper.

AFFIRMED.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

CATHIE WELLER, individually, and as the personal representative of the Estate of JAMES HETHERINGTON,	)	
Plaintiff,	)	**Civil Action No. CV-07-S-01706-NE**
vs.	)	
UNITED STATES OF AMERICA,	)	
Defendant.	)	

ORDER

(Filed Nov. 18, 2009)

In accordance with the memorandum opinion entered contemporaneously herewith, defendant's motion to exclude the testimony and opinions of plaintiff's experts, and for summary judgment (doc. no. 49) is GRANTED, and all of plaintiff's claims are dismissed with prejudice. Plaintiff's motion to exclude the testimony of defendant's expert, and for partial summary judgment (doc. no. 52) is DENIED as moot. Costs are taxed as paid. The Clerk is directed to close this file.

DONE and ORDERED this 18th day of November, 2009.

/s/ Lynwood Smith
United States District Judge

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

CATHIE WELLER, individually, and as the personal representative of the Estate of JAMES HETHERINGTON,	)	
Plaintiff,	)	**Civil Action No. CV-07-S-01706-NE**
vs.	)	
UNITED STATES OF AMERICA,	)	
Defendant.	)	

MEMORANDUM OPINION

(Filed Nov. 18, 2009)

This action is based upon the Federal Tort Claims Act. *See* 28 U.S.C. § 1346(b)(1) and §§ 2671-2680. The plaintiff is Cathie Weller, who sues both individually and as personal representative of the estate of her deceased father, James Hetherington. Plaintiff's claims for alleged medical negligence ("malpractice") and wrongful death arise out of the treatment provided to her father by the healthcare providers employed at the Louis Stokes Veterans Administration Medical Center in Cleveland, Ohio ("Cleveland VAMC") during the months of July,

August, and September of 2003.[1] The case presently is before the court on cross motions. The United States of America ("defendant" or "the government") moves for summary judgment on all of plaintiff's claims,[2] arguing that plaintiff's administrative claim was not received by the appropriate federal agency within two years of her decedent's death and, as a result, plaintiff's claims are barred by the applicable statutes of limitation. *See* 28 U.S.C. § 2401(b), § 2675(a), and 28 C.F.R. § 543.30 *et seq.*[3] The government also seeks to exclude the testimony of plaintiff's medical witnesses on the issues of causation and the applicable standard of care, arguing that their opinions are not reliable.[4] *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

In like manner, plaintiff moves to exclude the opinions and testimony of the government's medical expert, but on the grounds that his report was untimely.[5] Plaintiff also moves for partial summary judgment on her medical negligence claim, arguing that, because defendant failed to identify in a timely manner an expert witness to address the issue of the applicable standard of care, plaintiff's evidence

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[1] *See* doc. no.1 (Complaint); doc. no. 23 (Amended Complaint).

[2] Doc. no. 49.

[3] *See* doc. no. 50, at 11-18.

[4] *Id.* at 18-24.

[5] *See* doc. no. 53, at 6-7.

concerning the negligence of Cleveland VAMC's health care providers was uncontroverted.[6] Upon consideration, and for the reasons discussed below, the government's motion to exclude the testimony and opinions of plaintiff's experts will be granted. In the absence of evidence to support plaintiff's theory of causation, the government's motion for summary judgment also must be, and accordingly will be, granted. Plaintiff's motions to exclude the testimony of the government's expert, and for partial summary judgment on the issue of negligence, will be denied as moot.

I. STANDARDS OF REVIEW

Federal Rule of Civil Procedure 56 provides that summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).[7] In other words, summary judgment is proper "after adequate time for discovery and upon motion,

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[6] *Id.* at 7-11.

[7] Rule 56 was recently amended in conjunction with a general overhaul of the Federal Rules of Civil Procedure. The Advisory Committee was careful to note, however, that the changes "are intended to be *stylistic only*." Adv. Comm. Notes to Fed. R. Civ. P. 56 (2007 Amends.) (emphasis supplied). Consequently, cases interpreting the previous version of Rule 56 are equally applicable to the revised version.

against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "In making this determination, the court must review all evidence and make all reasonable inferences in favor of the party opposing summary judgment." *Chapman v. AI Transport*, 229 F.3d 1012, 1023 (11th Cir. 2000) (*en banc*) (quoting *Haves v. City of Miami*, 52 F.3d 918, 921 (11th Cir. 1995)). Inferences in favor of the non-moving party are not unqualified, however. "[A]n inference is not reasonable if it is only a guess or a possibility, for such an inference is not based on the evidence, but is pure conjecture and speculation." *Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1983). Moreover,

> [t]he mere existence of some factual dispute will not defeat summary judgment unless that factual dispute is *material* to an issue affecting the outcome of the case. The relevant rules of substantive law dictate the materiality of a disputed fact. A genuine issue of material fact does not exist unless there is sufficient evidence favoring the nonmoving party for a reasonable jury to return a verdict in its favor.

Chapman, 229 F.3d at 1023 (quoting *Haves*, 52 F.3d at 921) (emphasis supplied). *See also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986) (asking "whether the evidence presents a sufficient disagreement to require submission to a jury or

whether it is so one-sided that one party must prevail as a matter of law").

When presented with cross motions for summary judgment, "[t]he court must rule on each party's motion on an individual and separate basis, determining, for each side, whether a judgment may be entered in accordance with the Rule 56 standard." 10A Wright, Miller & Kane, *Federal Practice and Procedure: Civil 3d* § 2720, at 335-36 (1998) (footnote omitted); *see also, e.g., Arnold v. United States Postal Service*, 649 F. Supp. 676, 678 (D. D.C. 1986). Further, the court is required to "relate all material facts in genuine dispute to the light most favorable to the party resisting summary judgment." *Serrano-Cruz v. DFI Puerto Rico, Inc.*, 109 F.3d 23, 24 (1st Cir. 1997) (citing *Sanchez v. Alvarado*, 101 F.3d 223, 225 n.1 (1st Cir. 1996)).

II. SUMMARY OF FACTS AND PROCEDURAL HISTORY

James Hetherington was a 59-year-old Caucasian male with a history of multiple medical problems, including focal mesangial proliferative glomerulonephritis[8]

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[8] *Nephritis* is "inflammation of the kidney." Dorland's *Illustrated Medical Dictionary* 1229 (Douglas M. Anderson *et al.* ed., 30th ed. 2003) ("**Dorland's**"). Glomerulo[-]nephritis is defined as "nephritis accompanied by inflammation of the capillary loops in the renal glomeruli. It occurs in acute, subacute, and chronic forms and may be secondary to hemolytic streptococcal infection. Evidence also supports possible immune or autoimmune

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with ANCA positive vasculitis,[9] coronary artery disease with myocardial infarction,[10] Sjögren's Syndrome,[11] hypertension,[12] dyslipidemia,[13] eczema,[14] and shingles.[15]

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mechanisms." *Id.* at 779. *Mesangial proliferative glomerulonephritis* is "a kidney disorder characterized by swelling and blood in the urine (dark urine). It is caused by inflammation of an internal kidney structure (glomerulus), and specifically an increase in number of certain glomerular cells (mesangial cells), accompanied by antibody deposits in the mesangium layer of the glomerular capillary." Dictionary.com, A.D.A.M. Medical Encyclopedia, http://www.drugs.com/enc/mesangial-proliferative-glomerulonephritis.html (last visited Nov. 6, 2009).

[9] *Vasculitis* is "the inflammation of a blood or lymph vessel." *Dorland's*, at 2009.

[10] A *myocardial infarction*, commonly called a heart attack or MI, is a "gross necrosis of the myocardium as a result of interruption of the blood supply to the area; it is almost always caused by atherosclerosis of the coronary arteries, upon which coronary thrombosis is usually superimposed." *Id.* at 928.

[11] *Sjögren's syndrome* is "a symptom complex of unknown etiology, usually occurring in middle-aged or older *women*, marked by the triad of keratoconjunctivitis sicca with or without lacrimal gland enlargement, xerostomia with or without salivary gland enlargement, and the presence of a connective tissue disease, usually rheumatoid arthritis but sometimes systemic lupus erythematosus, scleroderma, or polymyositis. An abnormal immune response has been indicated." *Id.* at 1832 (emphasis supplied).

[12] *Hypertension* is "high arterial blood pressure; various criteria for its threshold have been suggested, ranging from 140 mm Hg systolic and 90 mm Hg diastolic to as high as 200 mm Hg systolic and 110 mm Hg diastolic. Hypertension may have no known cause (essential or idiopathic h.) or be associated with other primary diseases (secondary h.)" *Dorland's*, at 889.

Mr. Hetherington first presented to the Cleveland VAMC for treatment in March of 2003, complaining of fatigue, cough, anemia, and renal failure.[16] During that admission, he was found to have focal mesangial proliferative glomerulonephritis with ANCA positive vasculitis and Sjogren's Syndrome: conditions

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[13] *Dyslipidemia* is "abnormality in, or abnormal amounts of, lipids and lipoproteins in the blood." *Id.* at 575.

[14] *Eczema* is "a pruritic papulovesicular dermatitis occurring as a reaction to many endogenous and exogenous agents, characterized in the acute stage by erythema, edema associated with a serous exudate between the cells of the epidermis (spongiosis) and an inflammatory infiltrate in the dermis, oozing and vesiculation, and crusting and scaling; and in the more chronic stages by lichenification or thickening or both, signs of excoriations, and hyperpigmentation or hypopigmentation or both." *Id.* at 588.

[15] *See* doc. no. 51 (Evidentiary Materials in Support of Defendant's Motion for Summary Judgment), Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003). *Herpes zoster,* or "shingles," is "an acute infectious, usually self-limited, disease believed to represent activation of a latent human herpes virus 3 in those who have been rendered partially immune after a previous attack of chicken pox. It involves severe neuralgic pain along the distribution of the affected nerve and crops of clustered vesicles over the area of the corresponding dermatome, and is usually unilateral and confined to a single or adjacent dermatomes. Postherpetic neuralgia may be a complication. In immunocompromised patients it may disseminate and be fatal." *Dorland's,* at 845.

[16] *See* doc. no. 51 (Evidentiary Materials in Support of Defendant's Motion for Summary Judgment), Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

that were treated with medications, including cytoxan and prednisone.[17]

In May of 2003, Mr. Hetherington had an episode of shingles after beginning a medication called plavix.[18]

In early July of 2003, Mr. Hetherington was admitted to the Cleveland VAMC for acute coronary syndrome with a myocardial infarction ("heart attack"), at which time intercoronary stents were implanted in blood vessels of his heart.[19] In order to control Mr. Hetherington's heart condition, doctors at the Cleveland VAMC prescribed multiple medications, including plavix, ticlid,[20] and a beta blocker called metoprolol.[21]

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[17] *See id.*

[18] *See id. Plavix,* generically known as "clopidogrel," is "an inhibitor of platelet aggregation. A variety of drugs that inhibit platelet function have been shown to decrease morbid events in people with established cardiovascular atherosclerotic disease as evidenced by stroke or transient ischemic attacks, myocardial infarction, unstable angina or the need for vascular bypass or angioplasty. This indicates that platelets participate in the initiation and/or evolution of these events and that inhibiting them can reduce the event rate." Thompson Healthcare, *Physician's Desk Reference, Prescription Drugs,* Database updated February 2009, at 7308-1610 ("Physician's Desk Reference").

[19] *See* doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), at 22. *See also supra* note 10.

[20] *Ticlid,* generically known as "ticlopidine hydrochloride," is "a platelet aggregation inhibitor." Thompson Healthcare, *Physician's Desk Reference, Prescription Drugs,* Database updated August 2008, at 6920-2800. "When taken orally, ticlopidine

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On July 23, 2003, Mr. Hetherington complained of a rash.[22] Because the rash improved when plavix was discontinued, the rash was thought to be the result of that medication; Ticlid also was discontinued because the rash worsened with its administration.[23]

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hydrochloride causes a time-and dose-dependent inhibition of both platelet aggregation and release of platelet granule constituents, as well as a prolongation of bleeding time." *Id.*

[21] *See* doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003); doc. no. 56 (Evidentiary Materials in Support of Plaintiff's Response to Defendant's Motion for Summary Judgment), Ex. 9 (Deposition of Dr. Gelles), at 37. *Metoprolol* is

> a betal-selective (cardioselective) adrenergic receptor blocking agent. This preferential effect is not absolute, however, and at higher plasma concentrations, metoprolol also inhibits beta2-adrenoreceptors, chiefly located in the bronchial and vascular musculature. Metoprolol has no intrinsic sympathomimetic activity, and membrane-stabilizing activity is detectable only at plasma concentrations much greater than required for beta-blockade. Animal and human experiments indicate that metoprolol slows the sinus rate and decreases AV nodal conduction. Clinical pharmacology studies have confirmed the beta-blocking activity of metoprolol in man, as shown by *(1) reduction in heart rate and cardiac output at rest and upon exercise, (2) reduction of systolic blood pressure upon exercise, (3) inhibition of isoproterenol-induced tachycardia, and (4) reduction of reflex orthostatic tachycardia.*

Physician's Desk Reference, at 0400-4000 (emphasis supplied).

[22] *See* doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

[23] *See id.* The withdrawal of these two drugs, plavix and ticlid, apparently was a clinical procedure that the Eleventh

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One month later, on August 24, 2003, Mr. Hetherington again was admitted to the Cleveland VAMC with multiple complaints, including the presence of a worsening rash on his chest, arms, legs, and trunk, as well as diarrhea, nausea, and vomiting.[24] His physicians formed the impression that the rash was due to a reaction to medication, identifying the three most likely candidates for the offending drug as "plavix *versus* ticlid *versus* metoprolol."[25] Upon admission, all outpatient medications were discontinued except for prednisone, cytoxan, and clonidine,[26] and Mr. Hetherington was given lansoprazole, a proton pump inhibitor, from August 24th through the 29th.[27] He was also treated for an underlying infection with levofloxacin, an antibiotic, on August 30th and 31st, and vancomycin, another antibiotic, from August 28th

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Circuit described as a "dechallenge test" in *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) ("A test is a 'dechallenge' test when a drug that is suspected of causing a certain reaction is withheld to see if the reaction dissipates.").

[24] *See* doc. no. 51, Ex. 2 (Deposition of Cathy Weller), Ex. 6 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

[25] *See* doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 72; Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2003).

[26] *See* doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion to Exclude Dr. Alvin [sic] Goldstein, M.D. and Motion for Summary Judgment), Ex. A. (Report of Dr. Elewski), at 1.

[27] *See id.*

through the 31st.[28] On August 29th, the dermatology service noted in Mr. Hetherington's medical records that a laboratory evaluation of a skin biopsy performed four days earlier was consistent with a drug-related rash.[29]

On September 1st, Dr. Ellen Gelles, Mr. Hetherington's primary treating physician at the Cleveland VAMC, recorded that he was feeling much better "with improvement in weakness and resolution of diarrhea."[30] She also recorded that she had discussed the possibility of restarting some of Mr. Hetherington's cardiac medications, although she "planned to hold off for today, as this is the first day he is improving."[31] During her deposition in connection with this case, Dr. Gelles testified that, throughout the course of Mr. Hetherington's treatment, he was "intermittently very tachycardic while in the hospital [*i.e.*, his heart beat was excessively rapid[32]], which

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[28] *See id.*

[29] *See* doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 72, and Ex. 1 (Cleveland VAMC Medical Records dated Aug. 29, 2003).

[30] Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Cleveland VAMC Medical Records dated Sept. 1, 2003).

[31] *Id.*

[32] *Tachycardia* is "excessive rapidity in the action of the heart; the term is usually applied to a heart rate above 100 beats per minute in an adult and is often qualified by the locus of origin as well as by whether it is paroxysmal or nonparoxysmal." *Dorland's*, at 1850.

is dangerous for somebody who has just had a heart attack."[33]

The following day, September 2nd, Dr. Gelles resumed administration of metoprolol, the beta blocker that had been prescribed following Mr. Hetherington's heart attack in early July.[34] She recorded in his medical chart that the "[b]ig intervention was to re-start beta blocker, *as this was unlikely the culprit for hypersensitivity syndrome,* and he is less than 2 months out [from myocardial infarction]."[35] In her deposition, Dr. Gelles elaborated on her written explanation for the decision to resume administration of metoprolol by saying that "it is the standard of care to give beta blockers after a myocardial infarction to prevent death."[36] Dr. Gelles testified that metoprolol was "an essential medication and unlikely to be the cause of his rash . . . because beta blockers are not common causes of drug rashes."[37] On the same day, however, Dr. Genes also noted in medical records that

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[33] Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 44.

[34] *Id.* at 48-49.

[35] *Id.*, Ex. 1 (Cleveland VAMC Medical Records dated Sept. 2, 2003) (emphasis supplied). As noted in *Rider v. Sandoz Pharmaceuticals, see supra* note 23 (discussing a "dechallenge test"), the resumption of a drug that was discontinued in order to see if a reaction dissipates constitutes a "rechallenge test." *See* 295 F.3d at 1199 ("The drug may then be reintroduced in a 'rechallenge' to see if the reaction reoccurs.").

[36] *See* doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 37; 41-42.

[37] *Id.*

she had engaged in an "extensive discussion with [Mr. Hetherington and his] wife regarding uncertainties surrounding diagnosis (e.g. which drug caused this, expected course from here, etc)."[38]

On September 4th, two days after resumption of metoprolol, Dr. Gelles documented that Mr. Hetherington' s clinical status had not changed significantly, and that she had another long discussion with him, his wife, and their daughter (plaintiff herein) about Mr. Hetherington's medical status.[39]

Medical records for the following day, September 5th, reflected that Mr. Hetherington's symptoms and appearance had improved, and that his dosage of metoprolol was increased.[40] Mr. Hetherington also reported that he continued to feel better, despite significant sloughing of the skin on his legs.[41]

Two days later, on September 7th, Mr. Hetherington's medical records reflected that, even though he complained of increased urinary frequency, sleeplessness, and tremor, he denied feeling pain.[42] The

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[38] *Id.*

[39] *Id.*, Ex. 1 (Cleveland VAMC Medical Records dated Sept. 4, 2003).

[40] *Id.* (Cleveland VAMC Medical Records dated Sept. 5, 2003).

[41] *Id.* (Cleveland VAMC Medical Records dated Sept. 6, 2003).

[42] *See* doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), Ex. 4 (Cleveland VAMC Medical Records dated Sept. 7, 2003).

examining physician, medical student Benjamin Lind, again documented that Mr. Hetherington was "[o]verall feeling better."[43] Dr. Genes concurred, noting that "[o]verall, condition [was] improving."[44]

On September 8th, Mr. Hetherington began experiencing diarrhea, but the rheumatologist who examined him noted that his rash was resolving.[45] The medical records indicated that Mr. Hetherington was "upset over [his] current state," and that he (Mr. Hetherington) believed "it was due to metoprolol, which he now refuses to take."[46] Later on the same day, Mr. Hetherington "was adamant that [his] urinary frequency and agitation [were] due to metoprolol, and he insisted on being switched from metoprolol to clonidine for [blood pressure] control."[47] Dr. Gelles testified that she documented Mr. Hetherington's refusal of metoprolol because she "felt that metoprolol was the preferred medication to be given in the setting of a patient who had a previous recent myocardial infarction."[48] Nevertheless, due to Mr. Hetherington's refusal, the administration of metoprolol was discontinued against doctors' recommendations.

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[43] *Id.*

[44] *Id.*

[45] *See* doc. no. 51, Ex. 2 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 8, 2003).

[46] *Id.*

[47] *Id.*

[48] Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 55.

On September 9th, Mr. Hetherinton continued to complain of urinary frequency, but his records reflected a slight improvement in his skin condition.[49]

On September 11th, Mr. Hetherington's medical records reflected his desire to have his case reviewed for a second opinion.[50] His medical chart documents that he reiterated this desire the following day.[51] On both occasions, Dr. Gelles spoke with Mr. Hetherington and his wife about his options for obtaining a second opinion.[52] Dr. Genes noted that "patient's wife (and to a lesser extent, Mr. Hetherington) are expressing a lot of frustration that 'he is not better.' "[53] Later in the same notation, Dr. Gelles wrote that she "welcomed them to pursue transfer to the CCF [*i.e.*, Cleveland Clinic Foundation] if they would like."[54]

The records for September 12th show that Mr. Hetherington's skin remained "diffusely erythematous[55] and desquamating,"[56] and that he was

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[49] *See* doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 9, 2003).

[50] *Id.* (Cleveland VAMC Medical Records dated Sept. 11, 2003).

[51] *Id.* (Cleveland VAMC Medical Records dated Sept. 12, 2003).

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *Erythema* is "redness of the skin produced by congestion of the capillaries." *Dorland's,* at 638.

[56] *Disquamation* is defined as exfoliation. *Id.* at 501.

"tachycardic and slightly hypertensive and afebrile."[57] The following day, the medical records showed that, even though Mr. Hetherington was tachycardic, he continued to refuse the beta blocker metoprolol to control his heart condition, and that he was "currently on clonidine only for [blood pressure] control."[58]

According to notations made by Dr. Gelles in Mr. Hetherington's medical records two days later, on September 14th, his skin condition changed.[59] Dr. Gelles found diffuse bullae,[60] which she described as big blisters on Mr. Hetherington's skin.[61] Dr. Gelles wrote: "will consider having dermatology re-examine the skin, though I suspect that the new bullae are all

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[57] *See* doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 12, 2003). *Tachycardia* was defined in note 32, *supra*, as "excessive rapidity in the action of the heart; the term is usually applied to a heart rate above 100 beats per minute in an adult and is often qualified by the locus of origin as well as by whether it is paroxysmal or nonparoxysmal." *Hypertension* was defined in note 12, *supra*, as "high arterial blood pressure; various criteria for its threshold have been suggested, ranging from 140 mm Hg systolic and 90 mm Hg diastolic to as high as 200 mm Hg systolic and 110 mm Hg diastolic. Hypertension may have no known cause (essential or idiopathic h.) or be associated with other primary diseases (secondary h)." *Afebrile* means "without fever." *Dorland's*, at 36.

[58] *See* doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 13, 2003).

[59] *See* doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 60-61.

[60] A *bulla* is "a large elevation of the skin, containing serous or seropurulent fluid." *Dorland's*, at 259. *Diffuse* means "not definitely localized; widely distributed." *Id.* at 516.

[61] *See* doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), at 60-61.

part of normal resolution of this erythrodermic drug reaction."[62] Dr. Gelles also noted that, "if [patient is] agreeable, re-initiation of beta blocker would be helpful in this man who so recently had a coronary ischemic event."[63] The record shows that beta blocker metoprolol was in fact re-initiated that same day, September 14th, and it was administered to Mr. Hetherington along with fourteen other medications.[64]

On September 15th, Dr. Gelles observed that the patient "appears overall worse today, with continued tachycardia and rupture of the bullous lesions noted on skin yesterday."[65] Dr. Gelles discussed the case with the attending dermatology physician, Dr. Kevin Cooper, and wrote that Dr. Cooper's "clinical impression is that [Mr. Hetherington] has Stevens Johnson/TEN."[66] Stevens-Johnson syndrome is

> a sometimes fatal form of erythema multiforme having a flulike prodrome and systemic as well as more severe mucocutaneous lesions. Oronasal and anogenital mucous membranes may develop a characteristic gray or white pseudomembrane, and hemorrhagic crusts often occur on the lips. Ocular

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[62] *Id.*

[63] Doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 14, 2003).

[64] *Id.*

[65] *Id.* (Cleveland VAMC Medical Records dated Sept. 15, 2003).

[66] *Id.*

> lesions may include injected conjuctivitis, iritis, uveitis, corneal vesicles, erosions, and perforation, which may result in corneal opacities and blindness. Pulmonary, gastrointestinal, cardiac, and renal involvement also occur.[67]

"TEN," the acronym for toxic epidermal necrolysis, is

> an exfoliative skin disease seen primarily in adults as a severe cutaneous reaction to various factors, usually drugs but sometimes infections (viral, bacterial, or fungal), neoplastic disease, graft-versus-host reaction, or chemical exposure. It is characterized by full-thickness epidermal necrosis, resulting in subepidermal separation, bulla formation, and dermal inflammatory changes; there is widespread loss of skin, leaving raw areas where the skin surface looks scalded.[68]

Dr. Gelles noted that, "[i]f biopsies taken today indeed reveal TEN, and clinical status does not improve, [Mr. Hetherington] may need transfer to Metro Burn Unit."[69]

In the early afternoon of the same day, September 15th, Mr. Hetherington was transferred to the Cleveland VAMC intensive care unit ("ICU").[70] At that

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[67] *Dorland's*, at 1833.

[68] *Id.* at 1224.

[69] Doc. no. 51, Ex. 1 (Deposition of Cathie Weller), Ex. 7 (Cleveland VAMC Medical Records dated Sept. 15, 2003).

[70] *See id.*

time, his medical chart recorded that his skin rash had become "significantly worse, with ruptured bullae and extensive weeping."[71] Shortly after the transfer to ICU, the dermatologist reported that Mr. Hetherington's biopsy was consistent with Stevens Johnson Syndrome, with suspected progression to toxic epidermal necrolysis, or "TEN."[72]

By the next morning, September 16, 2003, Mr. Hetherington's "skin lesions were clearly progressing," and his respiratory status was becoming "more compromised."[73] At approximately 2:15 that afternoon, he was transferred from Cleveland VAMC's intensive care unit to the burn unit at a non-governmental hospital, MetroHealth Medical Center ("MetroHealth").[74] Upon his arrival, "he was felt to be in florid septic shock."[75] The admission records indicated that Mr. Hetherington had "intense reddening of the skin on all surfaces, no current bullae, but areas where bullae likely were now popped, leaking copious amount of serous fluids from all extremeties and trunk."[76] At 3:00 p.m., Mr. Hetherington was still in the admission area having his wounds treated

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[71] *Id.*

[72] *See id.*

[73] Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2009).

[74] *Id.*

[75] *Id.*

[76] *Id.*

when he went into asystolic arrest.[77] He could not be revived, and was pronounced dead shortly thereafter.[78]

Dr. Charles J. Yarrow, who had briefly evaluated and treated Mr. Hetherington at the MetroHealth Medical Center burn unit, explained to plaintiff that her father had developed toxic epidermal necrolysis while he was being treated at the VA Hospital, and that the condition had caused his death.[79] The death certificate signed by the Cuyahoga County, Ohio Medical Examiner on September 30, 2003, and issued on October 1, 2003, indicated that Mr. Hetherington's cause of death was "Toxic epidermal necrolysis ('TEN') due to multiple prescribed medications (Plavix, Ticlid, and/or Metoprolol)."[80]

Cathie Weller mailed an administrative claim to the Department of Veterans Affairs on Standard Form 95 by means of certified, priority mail on September 9, 2005, seven days prior to the second anniversary of her father's death.[81] For some reason unknown to the U.S. Postal Service, the claim form was not delivered within the guaranteed two-to-three

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[77] *See id. Asystole* is the "absence of a heartbeat." *Dorland's*, at 170.

[78] *See id.*

[79] Doc. no. 56, Ex. 9 (Deposition of Dr. Gelles), Ex. 1 (Medical Records dated Sept. 16, 2009).

[80] *See* doc. no. 51, Ex. 1 (Certificate of Death).

[81] *See* doc. no. 51, Ex. 1 (Certified Mail Receipt dated 09/09/2005). *82*

day period. In fact, the postal service did not attempt to deliver the parcel until the peculiar time and date of 3:46 a.m. on Sunday, September 18, 2005.[82] The parcel was finally received by the VA Office of Regional Counsel in Washington, D.C. on September 20, 2005.[83] The VA Office of Regional Counsel in Cleveland, Ohio received the administrative claim on September 28, 2009.[84] Because the delivery of plaintiff's parcel occurred well outside of the U.S. Postal Service's normal procedures, the Postmaster provided plaintiff a statement accepting responsibility for the delay, and requesting the receiving party, the Department of Veterans Affairs, to consider the parcel as having been delivered in a timely manner.[85]

The Department of Veterans Affairs formally denied plaintiff's claim on November 30, 2006.[86] Plaintiff filed her request for reconsideration on December 21, 2006, and received a notice of final denial on March 29, 2007.[87] Plaintiff filed her complaint in this court less than six months later, on September 19, 2007.[88]

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[82] *See* doc. no. 51, Ex. 1 (Track & Confirm Search Results).

[83] *See* doc. no. 51, Ex. 1 (Statement of Postmaster, Cynthia Obrien).

[84] *See id.*

[85] *See id.*

[86] *See* doc. no. 51, Ex. 1 (Letter of Denial).

[87] *See* doc. no. 51, Ex. 1 (Request for Reconsideration) and (Final Notice of Denial).

[88] Doc. no. 1.

On March 4, 2008, the court entered a scheduling order that established deadlines by which the parties were required to designate their expert witnesses pursuant to Federal Rule of Civil Procedure 26(a)(2).[89] That order incorporated the report of the parties' planning meeting, which provided for disclosure of plaintiff's retained experts by July 1, 2008, and defendant's retained experts by September 2, 2008.[90] On June 10, 2008, the court extended by sixty days the deadlines contained in the original scheduling order.[91]

Plaintiff designated her expert witnesses on August 29, 2008, in accordance with the scheduling order. Specifically, plaintiff designated Dr. Edward Taylor, an internist, to offer opinions regarding alleged breaches of the applicable standard of care by agents and employees of the United States.[92] At the same time, plaintiff designated a dermatologist, Dr. Alan Moshell, to provide opinions primarily regarding causation issues, but also concerning defendant's compliance with the applicable standard of care.[93]

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[89] Doc. no. 26.

[90] *See id.*

[91] *See* doc. no. 32 (Motion for Extension of Time); order entered on June 10, 2008 granting motion for extension of time.

[92] *See* doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion to Exclude Dr. Alvin [sic] Goldstein, M.D. and Motion for Summary Judgment), Ex. A. (Report of Dr. Edward Taylor).

[93] *See* doc. no. 54., Ex. B (Report of Dr. Alan Moshell).

On the date for disclosing its expert witnesses, the government designated a single medical witness, Dr. Boni Elewski, a dermatologist. Dr. Elewski's report primarily addressed issues of causation.[94] The government filed a second Rule 26 disclosure on February 2, 2009, which identified a new medical witness, Dr. Allan Goldstein.[95] Dr. Goldstein's report addressed issues relating to compliance with the standard of care.[96]

III. DISCUSSION

A. The Statute of Limitations

The United States, as sovereign, "is immune from suit save as it consents to be sued . . . and the terms of its consent to be sued in any court define the court's jurisdiction to entertain the suit." *Lehman v. Nakshian*, 453 U.S. 156, 160 (1980) (quoting *United States v. Testan*, 424 U.S. 392, 399 (1941)) (internal quotation marks omitted). The Federal Tort Claims Act ("FTCA") provides a limited waiver of the United States' sovereign immunity from tort claims for

> money damages . . . for injury or loss of property, or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Government while

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[94] *See* doc. no. 54, Ex. E (Report of Dr. Boni Elewski).

[95] *See* doc. no. 54, Ex. F (Defendant's Amended Initial Disclosures).

[96] *See* doc. no. 54, Ex. G (Report of Dr. Allan Goldstein).

> acting within the scope of his office or employment under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law of the place where the act or omission occurred.

28 U.S.C. § 1346(b). The applicable statute of limitation reads as follows:

> A tort claim against the United States shall be forever barred unless it is presented in writing to the appropriate Federal Agency *within two years after such claim accrues* or unless action is begun within six months after the date of mailing, by certified or registered mail, of notice of final denial of the claim by the agency to which it is presented.

28 U.S.C. § 2401(b) (emphasis supplied); *see also id.* § 2675(a) and 28 C.F.R. § 543.30 *et seq.*

Claims for medical negligence under the FTCA are deemed to accrue "when a claimant discovers, or in the exercise of reasonable diligence should have discovered, the acts constituting the alleged malpractice." *Burgess v. United States*, 744 F.2d 771, 773 (11th Cir. 1984) (citations omitted); *see also Price v. United States*, 775 F.2d 1491, 1494 (11th Cir. 1985) (holding that "a medical malpractice claim under the FTCA accrues when the plaintiff is, or in the exercise of reasonable diligence should be, aware of both her injury and its connection with some act of the defendant"). This principle has been extended to wrongful death claims under the FTCA, and such claims are

deemed to accrue "when the plaintiff knows, or exercising reasonable diligence should know, both of the decedent's death and its causal connection with the government." *Diaz v. United States*, 165 F.3d 1337, 1340 (11th Cir. 1999).

The government argues that plaintiff's claims are barred by the two-year statute of limitations quoted above, because her claims accrued on September 16, 2003, the date of Mr. Hetherington's death, and the federal agency did not receive plaintiff's administrative claims until September 20, 2005, four days past the two year anniversary of his death.[97]

Plaintiff argues, however, that the statute should run from October 1, 2003, the date of filing her father's death certificate (stating that Mr. Hetherington's cause of death was "Toxic epidermal necrolysis ('TEN') due to multiple prescribed medications (Plavix, Ticlid, and/or Metoprolol)").[98] Plaintiff explains that she was unaware of the connection between her

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[97] *See* doc. no. 50, at 11-18.

[98] *See* doc. no. 56, at 9. In response to defendant's first motion for summary judgment regarding the statute of limitations issue, plaintiff argued that the statute of limitations should run from the date on which the death certificate was signed, September 30, 2009. *See* doc. no. 8 (Plaintiff's Brief in Opposition to Defendant's Motion for Summary Judgment), at 4. The distinction between the two different dates that plaintiff has identified as the date of accrual, September 30th and October 1st, is immaterial for the purpose of evaluating the defendant's argument on the issue of the applicable statute of limitations.

father's death and the medications administered by the VA Medical Center "until after the death certificate was filed on October 1, 2003."[99]

This issue was first raised in a motion for summary judgment filed by the government in lieu of an answer to plaintiff's complaint.[100] Judge Clemon, to whom this action was assigned prior to his retirement, denied that motion on January 8, 2008, finding that "nothing in the evidence establishes that, on the date of her father's death, Ms. Weller became aware that the VA may have caused [his] death."[101] Judge Clemon found the existence of a genuine issue of material fact with respect to the precise date upon which plaintiff discovered or, in the exercise of reasonable diligence, should have discovered the acts constituting the alleged medical malpractice.[102]

In support of its present motion for summary judgment on this issue, the government relies upon the same arguments previously rejected by Judge Clemon. For example, the government emphasizes that Mr. Hetherington's medical records at the time of his death showed that a drug reaction causing TEN led to his death.[103] The only new evidence offered by

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[99] Doc. no. 56, at 9.

[100] *See* doc. no. 3 ("Defendant's First Motion for Summary Judgment," filed Oct. 30, 2007).

[101] Doc. no. 11, at 4.

[102] *See id.*

[103] *See* doc. no. 50, at 16.

the government is the fact that, during plaintiff's deposition, she "admits that she and other family members, on September 16, 2003, were informed by Dr. Yarrow at the Metro Hospital that Mr. Hetherington had TEN (toxic epidermal necrolysis) upon his arrival from the VA hospital and that this was the cause of his death."[104] The government then argues that, based upon the information conveyed by Dr. Yarrow, and the information available in Mr. Hetherington's medical records on the date of his death, plaintiff "knew or should have known to look to the VA doctors and other VA heath care providers for any responsibility in Mr. Hetherington's cause of death."[105] However, this court is not convinced that this evidence goes any further toward establishing that plaintiff either had discovered, or should have discovered, the acts constituting the alleged malpractice on the date of her father's death. To the contrary, plaintiff testified that, when she spoke to Dr. Yarrow just after the death of her father, she did not know what TEN was, and did not know that it was connected to drug reactions.[106]

The government also relies upon plaintiff's admission that, as early as September 12, 2003, she and other family members were "not happy" with the treatment given to Mr. Hetherington by the VA doctors

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[104] *Id* at 17.

[105] *See id.* at 16-17.

[106] *See* doc. no. 56, Ex. 7 (Deposition of Cathie Weller), at 25-26.

and other health care providers.[107] "Mere dissatisfaction with the results of medical treatment, however, is not to be equated with knowledge of negligence." *Waits v. United States*, 611 F.2d 550, 553 (5th Cir. 1980). In *Waits*, the former Fifth Circuit held that a plaintiff's FTCA claim was not time-barred after considering arguments similar to those asserted by the government in this case. *Id.*[108] The patient in *Waits* was treated for a broken leg at a VA hospital and developed an infection. *Id.* at 551. After becoming dissatisfied with the treatment he was receiving at the VA hospital, the patient was transferred to a non-government hospital on January 5, 1973. *Id.* There, it was determined that the antibiotic administered at the VA hospital was not an effective drug for treating the agent causing his infection. *Id.* Because of the delay in receiving an effective antibiotic, the infection had advanced to a stage that required amputation of the patient's leg. *Id.* An administrative claim was filed on January 24, 1975. *Id.* at 552. After suit was filed, the government argued that the case was time-barred because, on or about January 5, 1973, the patient knew that he had an infection and was dissatisfied with the VA hospital's medical treatment. *Id.* at 553. The court rejected this argument, holding that

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[107] *See* doc. no. 50, at 17.

[108] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (*en banc*), the Eleventh Circuit adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

the issue was not whether the patient had an infection, or was not satisfied with the course of his treatment, but whether on the date of transfer, the patient had reason to think that his infection had not been treated properly. *Id.*

Here, plaintiff knew on September 16, 2003 that her father had developed toxic epidermal necrolysis while receiving treatment at the Cleveland VAMC, and that the condition had caused his death.[109] Even so, those facts do not alone establish that plaintiff connected the actions of VA employees with the cause of her father's death. Accordingly, a genuine issue of material fact remains as to the precise date upon which plaintiff discovered or, in the exercise of reasonable diligence, should have discovered the acts constituting the alleged medical malpractice. Because it is not clear that plaintiff's claim accrued on September 16, 2003, the government is not entitled to summary judgment based upon its statute of limitations argument.

In response to the government's first motion for summary judgment on the statute of limitations issue, plaintiff argued that, even if the court were to decide that her claim accrued on September 16, 2003, her delay in filing an administrative claim should be excused because she submitted her claim via certified, priority mail on September 9, 2005 – seven days

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[109] *See* doc. no. 56, Ex. 7 (Deposition of Cathie Weller), at 25.

before the applicable statutory deadline.[110] Plaintiff argued that, because the U.S. Postal Service's inexplicable delay in delivering the parcel was beyond both her anticipation and ability to control, the four-day delay should not bar her claim.[111] However, plaintiff does not reiterate that argument in her opposition to the government's present motion for summary judgment. Although both parties acknowledge the Postal Service delay in their respective statements of fact,[112] neither the United States nor Ms. Weller address the issue in their present discussions of the statute of limitations issue. Because neither party cites any authority to support its position on the significance of the postal delay, the court will not address the possibility of equitable tolling.[113] Stated differently, the court will not speculate on what arguments might be made, especially when they are

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[110] *See* doc. no. 8, at 5-8.

[111] *See id.*

[112] *See* doc. no. 50, at 7-8; doc. no. 56, at 3, ¶ 9.

[113] *Compare Santos v. United States*, 559 F.3d 189, 197 (3rd Cir. 2009) (holding that the Federal Tort Claims Act's statute of limitations is not jurisdictional and, therefore, principles of equitable tolling applicable to suits against private defendants also applies to suits against the United States to "rescue a claim otherwise barred as untimely . . . when a plaintiff has been prevented from filing in a timely manner due to sufficiently inequitable circumstances") (citation and internal quotation marks omitted), *with Torjagbo v. United States*, 285 Fed. Appx. 615, 618 (11th Cir. 2008) (finding that the Federal Tort Claims Act's statute of limitations is jurisdictional, but declining to determine whether equitable tolling applies).

not fully developed or bolstered with legal authority. *See, e.g., U.S. Steel Corp. v. Astrue*, 495 F.3d 1272, 1287 n.13 (11th Cir. 2007) (refusing to address a party's "perfunctory and underdeveloped argument") (citing *Flanigan's Enterprises, Inc. v. Fulton County*, 242 F.3d 976, 987 n.16 (11th Cir. 2001) (holding that "fail[ure] to elaborate or provide any citation of authority in support [of an argument]" results in waiver)).[114]

B. The Government's Motion to Exclude the Opinion Testimony of Plaintiff's Medical Witnesses

Plaintiff's medical experts, Dr. Edward Taylor, an internist, and Dr. Alan Moshell, a dermatologist, reviewed the medical records regarding the administration of various medications to Mr. Hetherington, noted the condition of the patient at particular times, and concluded that metoprolol was the offending agent that caused the onset of toxic epidermal necrolysis.[115]

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[114] *See also Lyes v. City of Riviera Beach, Fla.*, 126 F.3d 1380, 1388 (11th Cir. 1997) (explaining that "the onus is upon the parties to formulate arguments"); *Resolution Trust Corp. v. Dunmar Corp.*, 43 F.3d 587, 599 (11th Cir. 1995) ("There is no burden upon the district court to distill every potential argument that could be made based upon the materials before it.").

[115] *See* doc. no. 54, Ex. A (Report of Dr. Edward Taylor); *id.*, Ex. B (Report of Dr. Alan Moshell).

Specifically, Dr. Taylor's report concludes that employees of the Cleveland Veterans Administration Medical Center breached the applicable standard of care by failing to appreciate that Mr. Hetherington's deteriorating medical condition was likely caused by metoprolol.[116] In support of this conclusion, Dr. Taylor points to the temporal proximity between the administration of metoprolol and the appearance of certain symptoms.[117] It is significant to note that Dr. Taylor does not mention any of the numerous other drugs administered to Mr. Hetherington around the time of his death, or any of his serious underlying medical conditions. Instead, Dr. Taylor simply concludes that continued administration of metoprolol was "by far the most likely inciting agent for the development of fatal Toxic Epidermal Necrolysis, sepsis and death in this unfortunate patient."[118] He states that Mr. Hetherington's death was the result of "poor medical management," and that compliance with the standard of care required that metoprolol be discontinued.[119]

In like manner, Dr. Moshell's report concludes that the continued administration of metoprolol was a breach of the standard of care and caused Mr. Hetherington's death.[120] Dr. Moshell's report does not

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[116] *See* doc. no. 54, Ex. A (Report of Dr. Edward Taylor), at 2.

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] *See* doc. no. 54, Ex. B (Report of Dr. Alan Moshell).

describe Mr. Hetherington's medical history, or the conditions from which he suffered. Like Dr. Taylor, Dr. Moshell's report fails to mention any of the numerous other drugs administered to Mr. Hetherington near the time of his death. Based solely upon a review of the administration of metoprolol, Dr. Moshell determined that metoprolol repeatedly caused allergic skin reactions resulting in the development of toxic epidermal necrolysis, complications of which ultimately caused Mr. Hetherington's death.[121] His report concludes:

> In summary, even though metoprolol is not a common cause of TEN [*toxic epidermal necrolysis*], in this case it is clear that it was the cause of Mr. Hetherington's TEN. Given the prior episodes of drug reaction to metoprolol, it was below the standard of care for it to have been administered in September of 2003. Had it not been administered, then TEN would not have developed, and Mr. Hetherington would not have died of complications of TEN.[122]

The government argues that the reports and testimony of both witnesses should be excluded on the ground that their opinions and theories of causation are not reliable.

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[121] *Id.*

[122] *Id.*

1. *The legal standards*

The starting point for any discussion of the admissibility of opinion testimony offered by so-called "expert witnesses" is Federal Rule of Evidence 702. As amended in 2000, in response to the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993),[123] *General Electric Co. v. Joiner*, 522 U.S. 136 (1997),[124] and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999),[125] Rule 702 now provides that:

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[123] The *Daubert* court made it clear that the requirement of reliability found in Rule 702 was the centerpiece of any determination of the admissibility of opinion testimony, 509 U.S. at 589, and the Court identified four factors to be used when determining the reliability of scientific evidence: (1) whether the theory can and has been tested; (2) whether it has been subjected to peer review; (3) the known or expected rate of error; and (4) whether the theory or methodology employed is generally accepted in the relevant scientific community. *Id.* at 593-94.

[124] In *Joiner*, the Court established the standard for reviewing trial court rulings of admissibility, and held that such rulings would be made under an abuse of discretion standard. 522 U.S. at 141. The Joiner court also established the important test of analytical "fit" between the methodology employed by an expert witness and the conclusions drawn. *Id.* at 146. The court reasoned that just because a methodology is acceptable for some purposes, it may not be acceptable for others, and a court may not admit evidence when there is "simply too great an analytical gap between the data and the opinion proffered." *Id.*

[125] In *Kumho Tire*, the Court made it clear that testimony based solely on the experience of an expert would not be admissible. 526 U.S. at 157. The expert's conclusions must be based on sound scientific principles, and the discipline itself must be a reliable one. *Id.* at 156. The key consideration is whether the

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> If scientific, technical, or other specialized knowledge *will assist the trier of fact* to understand the evidence or to determine a fact in issue, a witness *qualified as an expert* by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon *sufficient facts or data*, (2) the testimony is the product of *reliable principles and methods*, and (3) the witness has *applied* the principles and methods *reliably to the facts* of the case.

Fed. R. Evid. 702 (emphasis supplied). The requirements of this Rule can be grouped under three broad headings: *qualifications, reliability,* and *helpfulness. See, e.g., Frazier,* 387 F.3d at 1260; *Quiet Technology DC-8, Inc. v. Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1340 (11th Cir. 2003) (discussing the "three part inquiry [used] to determine the admissibility of expert testimony under Fed. R. Evid. 702").

Fidelity to the "gatekeeping role" imposed upon the trial court by the *Daubert* decision[126] requires district court judges to

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expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* The court emphasized that judges have considerable leeway in determining both how to test the reliability of evidence, and in deciding whether such evidence is reliable. *Id.* at 151-53.

[126] The *Daubert* decision held that the "general acceptance" test framed in *Frye v. United States*, 54 App. D.C. 46, 293 F.

(Continued on following page)

> engage in a rigorous inquiry to determine whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusion is sufficiently reliable as determined by the sort of inquiry mandated by *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue."

Rink v. Cheminova, Inc., 400 F.3d 1286, 1291-92 (11th Cir. 2005) (quoting *City of Tuscaloosa v. Harcros*

1013 (D.C. Cir. 1923), "should not be applied in federal trials" because it had been superseded by the Federal Rules of Evidence enacted by Congress in 1975. *Daubert*, 509 U.S. at 588-89 & n.6. *See also General Electric Co. v. Joiner*, 522 U.S. 136, 142 (1997) (observing that *Daubert* held "that the 'austere' *Frye* standard of 'general acceptance' had not been carried over into the Federal Rules of Evidence").

In place of the general acceptance standard, *Daubert* substituted *the trial court judge*, acting in the role of "gatekeeper" to the jury box, *see* 509 U.S. at 589 n.7, 597, and charged the judge with the "obligation" to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589. *See also id.* at 594 (observing that Rule 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"), and 597 (same).

In procedural terms, this means that the trial judge is required to conduct "a preliminary assessment" pursuant to Federal Rule of Evidence 104(a) as to "whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 593-94.

Chemicals, Inc., 158 F.3d 548, 562 (11th Cir. 1998) (footnote omitted)). *See also Frazier*, 387 F.3d at 1260 ("While there is inevitably some overlap among the basic requirements . . . they remain distinct concepts and the courts must take care not to conflate them.")[127] The burden of satisfying the district court that these three elements are present in a given case falls upon the party proffering the expert witness. *See, e.g., Rink*, 400 F.3d at 1292 ("The party offering the expert has the burden of satisfying these three elements by a preponderance of the evidence.") (citing *Allison v. McGhan Medical Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999)); *McDowell v. Brown*, 392 F.3d

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[127] It is important to understand that this categorization really is nothing more than a rearrangement and consolidation of the explicit requirements of Rule 702. The first and third prongs of the Eleventh Circuit's test (qualification and helpfulness, respectively) are taken from Rule 702's preamble. *See* Fed. R. Evid. 702 ("If scientific, technical, or other specialized knowledge *will assist the trier of fact* to understand the evidence or to determine a fact in issue, a witness *qualified as an expert* by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise. . . .") (emphasis supplied). The major change accomplished by the Eleventh Circuit's restatement is truncation of Rule 702's three-part litmus test for methodological reliability. *See* Fed. R. Evid. 702(1)-(3). Clearly, that does not mean that district courts are to *ignore* the explicit language of Rule 702; on the contrary, the Eleventh Circuit's formula simply recognizes that the three numbered prerequisites (and the additional thoughts imparted by the Supreme Court in *Daubert*) all relate to the same general concern: the reliability of the methodology utilized by the expert. Procedurally, then, the district court should consider satisfaction of those requirements separate and apart from qualification and helpfulness.

1283, 1298 (11th Cir. 2004) (same); *Frazier*, 387 F.3d at 1260 (same).

a. *Qualifications*

The court finds, and the government does not dispute, that both of plaintiff's medical experts are qualified by education and experience to offer opinion testimony. Therefore, the court need not discuss further Rule 702's qualifications requirement.

b. *Reliability*

The reliability inquiry mandated by Federal Rule of Evidence 702 has three parts: the district court must ensure that "(1) the testimony is based upon *sufficient facts or data*, (2) the testimony is the product of *reliable principles and methods*, and (3) the witness has *applied* the principles and methods *reliably to the facts* of the case." Fed. R. Evid. 702 (emphasis supplied). Below, the court will address each of these requirements, but not in the order of their appearance in Rule 702. *Cf. Allstate Insurance Co. v. Hugh Cole Builder, Inc.*, 137 F. Supp. 2d 1283, 1287 (M.D. Ala. 2001) ("Because Defendants' arguments concerning the sufficiency of the facts carry over into the application of the facts to the methods inquiry, the court will first examine whether the testimony is the product of reliable principles and methods[.]").

i. Reliable principles and methods

As a result of the Supreme Court's concern that jurors across the nation were at risk of being misled by purveyors of so-called "junk science," *General Electric Co. v. Joiner*, 522 U.S. 136, 153 (1997) (Stevens, J., concurring in part and dissenting in part), the *Daubert* opinion imposed upon district court judges the responsibility for conducting "a preliminary assessment of whether the reasoning or methodology underlying the [proffered expert's opinion] testimony is scientifically valid." *Daubert*, 509 U.S. at 592-93. *See also* Fed. R. Evid. 104(a) ("Preliminary questions concerning the qualification of a witness . . . or the admissibility of evidence shall be determined by the court[.]"). The Court acknowledged that "[m]any factors will bear on this inquiry," *Daubert*, 509 U.S. at 593, and emphasized the need to remain "flexible," *id.* at 594, but nevertheless went on to provide five "general observations" to assist district judges in assessing the reliability of the principles and methodology employed by a particular witness. *Id.* at 593. Specifically, the Court held that district judges may consider:[128] whether the theory or

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[128] In *Kumho Tire*, the Court clarified that "a trial court *should* consider the specific factors identified in *Daubert* [only] where they are reasonable measures of the reliability of expert testimony [at issue in the case]." *Kumho Tire*, 526 U.S. at 152 (emphasis supplied). *See also id.* ("The trial court must have the same kind of latitude in deciding *how* to test an expert's reliability . . . as it enjoys when it decides *whether or not* that expert's relevant testimony is reliable.") (emphasis in original).

technique in question can be (and has been) tested; whether it has been subjected to peer review and publication; its known or potential error rate; the existence and maintenance of standards controlling its operation; and whether the theory enjoys widespread acceptance within the relevant scientific community. *Id.* at 593-94. The Court emphasized that "the focus . . . must be solely on *principles* and *methodology,* not on the *conclusions* that they generate." *Id.* at 595 (emphasis supplied).

Both Dr. Taylor and Dr. Moshell claim to have used a methodology called "differential diagnosis" to reach their respective opinions in this case. In an affidavit filed almost eight months after the submission of his expert report, Dr. Taylor explained:

> As one typically does in trying to determine the cause of TEN [*toxic epidermal necrolysis*], a physician goes through the process of looking at all of the reasonable explanations for a patient's condition, and then determines through a process of elimination which cause is the most likely. This is commonly referred to as forming a "differential diagnosis." This is the process I used in examining Mr. Hetherington's medical records seeking the likely cause of his TEN.[129]

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[129] Doc. no. 56, Ex. 5 (Affidavit of Dr. Taylor), ¶ 4.

Dr. Moshell gave a strikingly similar explanation in his affidavit, which also was filed more than eight months after his expert report.[130]

The Eleventh Circuit addressed the methodology allegedly employed by Doctors Taylor and Moshell in *McClain v. Metabolife International, Inc.*, 401 F.3d 1233 (11th Cir. 2005), and defined it as follows:

> Differential diagnosis involves "the determination of which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their clinical findings." *Dorland's Illustrated Medical Dictionary* 240, (Douglas M. Anderson et al. ed., 29th ed. 2000). This leads to the diagnosis of the patient's condition, not necessarily the cause of that condition. *The more precise but rarely used term is differential etiology,* which is "a term used on occasion by expert witnesses or courts to describe the investigation and reasoning that leads to the determination of external causation, sometimes more specifically described by the witness or court as a process of identifying external causes by a process of

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[130] *See* doc. no. 56, Ex. 4 (Affidavit of Dr. Moshell), ¶ 4 ("As explained in my deposition, when determining the cause or etiology of a condition, a physician goes through a process commonly referred to as a 'differential diagnosis.' In doing so, one looks at the various possible explanation for a patient's condition and then determines which cause is the most likely one. This is the process I used in examining Mr. Hetherington's medical records, seeking the likely cause of TEN.").

> elimination." *See* Mary Sue Henifin et al., *Reference Guide on Medical Testimony*, in *Reference Manual on Scientific Evidence* 439, 481 (Federal Judicial Center, 2d ed. 2000). *The etiology of a disease is the cause or origin of the disease. . . .*

McClain, 401 F.3d at 1252 (emphasis added). Although several courts rightfully have noted that significant differences exist between the formation of a "differential *diagnosis*" of a patient's disease, and the process of seeking the "differential *etiology*" of the disease process, *see, e.g., Bowers v. Norfolk Southern Corp.*, 537 F. Supp. 2d 1343, 1360-62 (M.D. Ga. 2007),[131] courts generally have used the terms

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[131] As the Middle District of Georgia aptly observed in *Bowers v. Norfolk Southern Corp.*, 537 F. Supp. 2d 1343 (M.D. Ga. 2007), it is too easy to gloss over the distinctions between the definitions of the two terms, "differential diagnosis" and "differential etiology," and to

> conclude that they amount to a distinction without a difference. Indeed, courts in various circuits have admitted expert testimony supposedly based on the "differential diagnosis" method, when, in reality, the testimony is based on the "differential etiology" method. The distinction is more than semantic; it involves an important difference.
>
> The difference arises from what is at stake in the two distinct methods and what that difference implies about the likely reliability of the expert's opinions. When a doctor develops his differential diagnosis in treating a patient, two factors strongly insure that the doctor will follow a reliable methodology to diagnose the patient's condition. First, if he misdiagnoses the patient's condition, the patient may die. And second, if

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interchangeably when evaluating expert opinions. Therefore, even though this court finds that the term "differential etiology" more aptly describes the methodology used by Doctors Taylor and Moshell, the court will, nevertheless, use the term "differential diagnosis" for the purpose of consistency with published opinions.

Six Circuits have held that a medical opinion on causation that is based upon a reliable differential diagnosis is sufficiently reliable to be admissible under Rule *702. See Westberry v. Gislaved Gummi AB,* 178 F.3d 257, 262-63 (4th Cir. 1999) (collecting cases from the First, Second, Third, Ninth, and D.C. Circuits). The Third Circuit found that the technique

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> he misdiagnoses the patient's condition and the patient dies, then the patient's family will sue the doctor for medical malpractice.
>
> By contrast, when an expert witness uses the differential etiology approach to testify in court to support a litigant's case, he has very little at stake. He renders his opinion, and then gets paid, often quite handsomely. The plaintiff is at no risk of harm, and the expert will not get sued for malpractice.
>
> *The differential diagnosis method has an inherent reliability; the differential etiology method does not.* This conclusion does not suggest that the differential etiology approach has no merit. It simply means that courts, when dealing with matters of reliability, should consider opinions based on the differential etiology method with more caution. It also means that courts should not conflate the two definitions.

Id. at 1360-61 (footnotes omitted) (emphasis supplied).

consists of a testable hypothesis, has been subject to peer review, contains standards for controlling its application in a particular case, has widespread acceptance in the medical community, and does not frequently lead to incorrect results. *See Heller v. Shaw Industries, Inc.*, 167 F.3d 146, 154-55 (3d Cir. 1999); *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 758 (3d Cir. 1994).

On the other hand, the Eleventh Circuit has found "in the context of summary judgment that differential diagnosis evidence by itself does not suffice for proof of causation." *Rink*, 400 F.3d at 1295 (citing *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d at 1194, 1199 (11th Cir. 2002) (holding that even though some case reports "do contain details of the treatment and differential diagnosis," such reports, nevertheless, "are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert . . . because they report symptoms observed in a single patient in an uncontrolled context")).[132] The

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[132] The entire context of the excerpt from the *Rider* opinion quoted in text is as follows:

> Some case reports do contain details of the treatment and differential diagnosis. Even these more detailed case reports, however, are not reliable enough, by themselves, to demonstrate the causal link the plaintiffs assert that they do because they report symptoms observed in a single patient in an uncontrolled context. They may rule out other potential causes of the effect, but they do not rule out the possibility that the effect manifested in the reported patient's case is simply idiosyncratic or the result of

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Eleventh Circuit has not entirely rejected the differential diagnosis methodology, however, explaining that

> [u]nder certain circumstances, *circumstances that ensure reliability,* this approach may offer an important component of a valid methodology. This approach, however, will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm the plaintiff suffered.

McClain, 401 F.3d at 1252 (emphasis supplied). Although the *McClain* Court considered an expert's use of the differential diagnosis methodology in the context of a toxic tort case involving a diet drug, the court's reasoning has been applied to experts' differential diagnoses of causation in other contexts. *See, e.g., Bowers*, 537 F. Supp. 2d at 1360-63 (applying the

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> unknown confounding factors. As such, while they may support other proof of causation, case reports alone ordinarily cannot prove causation. *See, e.g., Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1165 (S.D. Fla. 1996) (stating that "while case reports may provide anecdotal support, they are no substitute for a scientifically designed and conducted inquiry." (citation omitted)), *aff'd without op.*, 158 F.3d 588 (11th Cir. 1998). The record demonstrates that the district court carefully considered the case reports and properly concluded that the case reports did not by themselves provide reliable proof of causation.

Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d at 1199.

methodology to the opinion of an orthopaedist regarding the causation of the plaintiff's back injury).

The Eleventh Circuit has made clear that an expert does not establish the reliability of his techniques or the validity of his conclusions simply by claiming that he performed a differential diagnosis on a patient. *See McClain*, 401 F.3d at 1253. Opinions based on a differential diagnosis are admissible only if the trial court determines that the expert reliably applied the differential diagnosis methodology. *See, e.g., Goebel v. Denver & Rio Grande Western Railroad Co.*, 346 F.3d 987, 999 (10th Cir. 2003); *see also Westberry*, 178 F.3d at 263 ("[A] *reliable* differential diagnosis provides a valid foundation for an expert opinion.") (emphasis supplied). Thus, in evaluating the reliability of an opinion based on a differential diagnosis, courts consider the substance of the expert's analysis, rather than just the label. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057-1058 (9th Cir. 2003). The *McClain* Court explained:

> No one doubts the utility of medical histories in general or the process by which doctors rule out some known causes of disease in order to finalize a diagnosis. But such general rules must . . . be applied fact-specifically in each case. *The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur.* Based on such predicate knowledge, it may then be possible

> to fasten legal liability for a person's disease or injury.

McClain, 401 F.3d at 1253 (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999) (emphasis and omissions in original).

ii. Application of principles and methodology to the facts

The Ninth Circuit's opinion in *Clausen v. M/V NEW CARISSA*, *supra*, provides a comprehensive test for determining the reliability of a medical expert's application of the differential diagnosis methodology to the facts of a particular case:

> The first step in the diagnostic process is to compile a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. *See* [Jerome P. Kassirer & Richard I. Kopelman, *Learning Clinical Reasoning* 112 (1991)]. The issue at this point in the process is which of the competing causes are generally capable of causing the patient's symptoms or mortality. Expert testimony that rules in a potential cause that is not so capable is unreliable. *See Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1413 (D. Or. 1996) ("[I]t is . . . important to recognize that a fundamental assumption underlying [differential diagnosis] is that the final, suspected 'cause' . . . must actually be capable of causing the injury."). Similarly, expert testimony that neglects to consider a hypothesis that might explain the

clinical findings under consideration may also be unreliable. Including even rare entities in the list "ensures that such disorders are not overlooked." *Clinical Reasoning*, *supra* n. 2, at 112; *see also Westberry*, 178 F.3d at 265 ("A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.").

After the expert rules in all of the potential hypotheses that might explain a patient's symptoms, he or she must then engage in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case. A district court is justified in excluding evidence if an expert "utterly fails . . . to offer an explanation for why the proffered alternative cause" was ruled out. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001). The expert must provide reasons for rejecting alternative hypotheses "using scientific methods and procedures" and the elimination of those hypotheses must be founded on more than "subjective beliefs or unsupported speculation." *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994).

Clausen, 339 F.3d at 1057-58.

(A) *Comprehensive list of hypotheses*

Both Dr. Taylor and Dr. Moshell fail the *Clausen* reliability test at step one. Neither doctor's report includes a list, much less a comprehensive list, of hypotheses that might explain the development of toxic epidermal necrolysis in Mr. Hetherington. Neither witness attempts to explain the physiological process by which toxic epidermal necrolysis develops, or the factors that cause it to occur. Instead, both experts admit that there is no medical literature (other than the possibility of anecdotal case reports) to support their theory that metoprolol causes toxic epidermal necrolysis. In fact, both Dr. Taylor and Dr. Moshell admit that there have been no specific studies showing metoprolol to be a cause of toxic epidermal necrolysis.[133] In contrast, defendant's expert, Dr. Boni Elewski, identified numerous, potential causes of the condition in her report:

> TEN [*toxic epidermal necrolysis*] can occur as a result of several factors including drugs, underlying malignancy, bacterial or viral infection, and idiopathic. The most common drugs which are known to cause TEN include antibiotics, allopurinol, NSAIDS (nonsteroidal anti-inflammatory drugs), and anticonvulsants. There are a variety of other miscellaneous drugs that [sic] such as proton

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[133] *See* doc. no. 56, Ex. 4 (Affidavit of Dr. Moshell); Ex. 5 (Affidavit of Dr. Taylor).

pump inhibitors which also might be culpable. Other etiologic cofactors include renal failure, immunosuppression and possibly underlying viral infections. Since TEN is idiosyncratic, its occurrence cannot be predicted.

The most common cause of TEN is drug-induced; antibiotics are often associated. Prior to the onset of TEN, Mr. Hetheringon was treated with levofloxacin (an antibiotic) on 8/30 and 8/31 for an underlying infection, as well as with vancomycin (an antibiotic) on 8/28 to 8/31. Additionally, he was given a proton pump inhibitor, lansoprazole, on 8/24 through 8/29, which is another common cause of TEN. (Blume *et al.*) The onset of TEN after the offending drug varies from patient to patient, but is usually 1 to 2 weeks. . . . The TEN started approximately 14 days after the administration of the antibiotics levofloxacin and vancomycin, and the lansoprazole, so the timing of the erruption is within the expected boundry. Although TEN is often an idiosyncratic hypersensitivity reaction to medication, it is often attributed to infection, and Mr. Hetherington had an underlying infection requiring the above mentioned antibiotic therapy. Additionally, he had underlying heath issues including glomerulonephritis (p-anca positive with

Sjogrens syndrome) requiring immunosuppressants, which could have contributed to the development of TEN.[134]

(B) *Process of elimination*

Although both of plaintiff's medical witnesses claim to have engaged in a process of elimination before reaching their conclusions, neither of their respective reports consider any alternative hypothesis. Neither Dr. Taylor nor Dr. Moshell even mention the fact that Mr. Hetherington was administered numerous medications in addition to metoprolol. When asked if he had ruled out levofloxacin, vancomycin, trimethoprin-sulfa, lansoprazole, autoimmune kidney disease, Sjogrens syndrome, or immunosuppressants as potential causes of Mr. Hetherington's development of toxic epidermal necrolysis, Dr. Taylor admitted that he had not ruled out those possible alternatives.[135] Dr. Moshell gave the same response during his deposition.[136]

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[134] Doc. no. 54 (Evidentiary Materials in Support of Plaintiff's Motion for Summary Judgment), Ex. E (Report of Dr. Elewski), at 1.

[135] *See* doc. no. 51, Ex. 4 (Deposition of Dr. Taylor), at 17-19.

[136] *See* doc. no. 51, Ex. 5 (Deposition of Dr. Moshell), at 23-24.

(C) *Reasons for rejecting alternative hypotheses*

Since neither doctor considered any alternative hypothesis for what may have led to the development of toxic epidermal necrolysis in Mr. Hetherington, it follows that they also failed to provide reasons for rejecting alternative hypotheses "using scientific methods and procedures." Because both Dr. Taylor and Dr. Moshell failed to apply the differential diagnosis methodology reliably in their respective evaluations of Mr. Hetherington's medical records, the court finds that their opinions do not meet the standard for reliability under Rule 702 and *Daubert* and are, therefore, due to be excluded.

c. *Assistance to the trier of fact*

The final requirement for admissibility of expert testimony under Rule 702 is that it assist the trier of fact. Testimony is only admissible if it concerns matters that are beyond the understanding of the average layperson. *See United States v. Rouco*, 765 F.2d 983, 995 (11th Cir. 1985). "Proffered expert testimony generally will not help the trier of fact when it offers nothing more than what lawyers for the parties can argue in closing arguments." *Frazier*, *387* F.3d at 1262-63.

As discussed in more detail above, Doctors Taylor and Moshell have not provided any medical justification for their conclusions, aside from the temporal proximity of the administration of metoprolol to

certain symptoms noted in Mr. Hetherington's chart. Neither doctor provides any information regarding the connection of metoprolol to toxic epidermal necrolysis, or the reasons why metoprolol was found to be a more likely cause of the disorder than any of the other numerous medications administered to Mr. Hetherington. Furthermore, the doctors' reports do not even mention the possible causes of toxic epidermal necrolysis, aside from disclosing that metoprolol is *not* a common cause. Both expert reports simply review notations made by the treating physicians at the Cleveland VAMC and make speculative opinions as to causation without disclosing any reasoning. The opinions of Dr. Taylor and Dr. Moshell, therefore, add nothing to plaintiff's case apart from what plaintiff's lawyers could argue to the jury.

Having failed to meet both the reliability and helpfulness prongs of the *Daubert* standard, the opinions of Doctors Taylor and Moshell are due to be excluded under Rule 702. Because plaintiff has presented no reliable evidence to demonstrate causation, plaintiff has not established a prima facie case. Accordingly, defendant's motion for summary judgment will be granted.

C. Plaintiff's Motion to Exclude Dr. Goldstein and Motion for Summary Judgment

Pursuant to this court's finding that plaintiff has failed to present a prima facie case, and the resulting

conclusion that summary judgment should be entered in favor of the government, plaintiff's motions will be denied as moot. An appropriate order consistent with this memorandum opinion will be entered contemporaneously herewith.

DONE this 18th day of November, 2009.

/s/ Lynwood Smith
United States District Judge